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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,198	04/02/2004	Kim Simelius	4208-4184	2178
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MORGAN & FINNEGAN, L.L.P. 3 WORLD FINANCIAL CENTER NEW YORK, NY 10281-2101			EXAMINER WHALEY, PABLO S	
			ART UNIT 1631	PAPER NUMBER
			NOTIFICATION DATE 09/18/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/817,198	SIMELIUS, KIM	
	<b>Examiner</b>	<b>Art Unit</b>	
	Pablo Whaley	1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-126 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 20, 21, 26-28, 34, 35 and 37-126 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-19, 22-25, 29-33, and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>04/26/2004 and 09/30/2004</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***APPLICANT'S ELECTION***

Applicant's election with traverse of Group I (Claims 1-36), Specie A (arrhythmia , as in claim 12), Specie B (cardiopulmonary system, as in claim 36), and Specie C (heart, as in claim 19), in the reply filed on 07/13/2007 is acknowledged. The traversal is on the grounds that the Examiner has not established an undue search burden. This is not found to be persuasive because the Examiner has clearly set for that Groups I-IV have different effects for Groups I and II, Groups III and IV, and that Groups [I and II] and Groups [III and IV] are distinct based on process and apparatus for its practice reasoning, as set forth in detail in the restriction requirement, mailed 01/17/2007. Furthermore, the examination process requires a search of non-patent literature, U.S. patent publications, U.S. patents, as well as foreign patent literature. The requirement is still deemed proper and is therefore made FINAL.

Claims 13, 14, 20, 21, 26-28, 34, 35, and 37-126 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07/13/2007.

### ***CLAIMS UNDER EXAMINATION***

Claims 1-12, 15-19, 22-25, 29-33, and 36 are herein under examination as they read upon the elected species.

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*INFORMATION DISCLOSURE STATEMENT*

The information disclosure statements filed 04/26/2004 and 09/30/2004 have been considered in full.

*PRIORITY*

Priority to the instant application's filing date 4/2/2004 has been acknowledged.

*DRAWINGS*

Drawings filed 04/02/2004 have been accepted.

**CLAIM REJECTIONS - 35 USC § 112, 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 15-19, 22-25, 29-33, and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4, 5, 7, 11, 17, and 33 are rejected for the following reasons. Claims which are directly or indirectly dependent from claim 1 are also included as rejected herein, due to said dependence.

Claim 1 recites "wherein deducing takes into account the selected operational mode." It is unclear in what way deducing "takes into account" the operational mode. Clarification is requested via clearer claim language.

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Claim 1: It is unclear whether applicant intends for said “user” to be one who is operating a simulated organ (i.e. operator), or one who is have their condition “deduced” (i.e. a patient). Clarification is requested via clearer claim language.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are between “selecting an operational mode” and “deducing a condition of the user.” As model-based condition deduction typically requires a comparison of control data and experimental data, it is unclear in what way operational mode selection relates to deducing a condition. Clarification is requested.

Claim 4: The term “is like” is a relative term of degree, therefore it is unclear how “like” a process need to be in order to be considered “like that of a reduced lead set electrocardiogram.” Clarification is requested.

Claim 5: It is unclear in what way a simulated organ is simulated “at a wireless node.” Clarification is requested.

Claim 7 recites “a plurality of organs are simulated.” However, as parent claim 1 recites “simulating an organ”, it is unclear in what way the said “plurality of organs” further limits the claimed “organ.” Clarification is requested.

Claims 11 and 17: It is unclear what limitation is intended by “the simulated organ simulates the organ of the user” due to the use of circular reasoning. Clarification is requested.

Claim 33 recites “a body system is simulated.” However, as parent claim 1 recites “simulating an organ”, it is unclear in what way the said “body system” further limits the claimed “organ.” Clarification is requested.

### CLAIM REJECTIONS - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12, 15-19, 22-25, 29, 32, 33, and 36 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons.

The instant claims are directed to a method comprising steps of operating a simulated organ, obtaining measurement data, selecting an operational mode, and deducing a condition of the user. According to the revised Guidelines, a claimed invention directed to a statutory process must provide: (1) a practical application by physical transformation (i.e. reduction of an article to a different state or thing), or (2) a practical application that produces a concrete, tangible, and useful result. As written, the claimed method steps may be achieved *in-silico* and therefore do not result in a physical transformation of matter. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. real-world), and useful result (i.e. a specific and substantial). However, claim 1 results in a step of “deducing a condition of a user” but does not recite limitation wherein a real-world result is necessarily communication to a user. Therefore, the instant claims do not recite a practical application of a 35 U.S.C. 101 Judicial exception and therefore are not statutory. This rejection could be overcome by amending the claims to recite a “tangible” (i.e. real-world result), as recited in claims 30 and 31. For exemplary purposes only, applicant would likely overcome this rejection by amending the claims to recite one of the following: (1) a step wherein the result of the claimed method is communicated to a user (i.e.

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real-world result), graphically displayed, or output (e.g. to a user, to a memory, or to another computer); or (2) by amending the claims to include of a physical transformation of matter (e.g. assay). For an updated discussion of statutory considerations, see the revised Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV (Latest Revision August 2006).

#### *PRIOR ART REJECTION OF INDEFINITE CLAIMS*

In view of the indefiniteness and lack of clarity in the instant claims, as set forth in the 35 USC 112 2<sup>nd</sup> rejections above, the Examiner has had difficulty in properly interpreting the claimed invention. However, to avoid piecemeal prosecution and to give applicant a better appreciation for relevant prior art if the claims are redrafted to avoid the 35 USC 112 2<sup>nd</sup> rejections, the Examiner has broadly interpreted the claims for purposes of applying the following prior art rejections.

#### **CLAIM REJECTIONS - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1-4, 7-12, 15-17, 19, 22-23, 29, 30, 32, 33, and 36 are rejected under 35 U.S.C. 102 (b) and (e) as being anticipated by Eggert et al. (US 6,527,558; Issued Mar. 4, 2003; Filed Aug. 17, 2000).

The instant claims are directed to a method comprising steps for operating a simulated organ, obtaining measurement data, selecting an operational mode, and deducing a condition of the user, wherein the condition is arrhythmia (as required by Specie A and as in claim 12), wherein the simulated organ is a heart (as required by Specie C and as in claim 19), and wherein a cardiopulmonary system is simulated (as required by Specie B and as in claim 36).

Eggert et al. teach an interactive method for teaching patient care to a user [Abstract] and [Fig. 1a] comprising: simulating a plurality of conditions with a patient simulator; using a virtual instrument with the patient simulator; sensing an interaction between the virtual instrument and the simulator, and providing feedback to the user regarding the interaction between the virtual instrument and the simulator. In particular, Eggert et al. teach the following aspects of the instantly claimed invention as they read upon Species A, B, and C:

Operating a patient simulator [Abstract] which includes a simulated organs include the heart, lungs, and other organs [Col. 4, lines 45-50], as in claims 1, 2, 7, 19 and Specie C.

ECG sensors comprising a multi-lead system for obtaining biological measurement data and means for sensor calibration [Col. 4, lines 35-45], as in claims 1, 3, 4, and 22-23.

Selection of arrhythmia modules (i.e. operational modes) [Fig. 12] and [Fig. 5] for providing information regarding measured biological data in the form of arrhythmias, treatment, EKG sounds, trace, and exit items [Col. 12, lines 1-15], as in claims 1, 12, 32, and Specie A.

Selection of a shock button (i.e. operational mode) for simulating defibrillation shock such that the resultant condition matches biological data [Col. 5, lines 10-20], as in claim 1.



Simulating the cardiopulmonary system and deducing the condition of a user by manipulation of operational modes [Fig. 18, 20, and 21], which is a teaching for “deducing a condition of the user” that takes into account an operational mode, as in claims 1, 33, 36 and Specie B.

Providing feedback to the user regarding the interaction between the virtual stethoscope and the simulator comprises a predetermined realistic body sound when the virtual stethoscope is placed on the correct anatomical position of the simulator [See Ref. Claim 31], which is broadly interpreted as a teaching for calibration such that the output signal share one or more characteristics with the biological measurement data, as in claim 3.

Simulation of the thorax [Fig. 19], as in claim 8. Simulating vital signs with a module that simulates a plurality of cardiac rhythms for a user to analyze and determine as normal or abnormal [Col. 15, lines 35-45], as in claims 9, 10, 11, 15, 16, and 17. Employing waveform comparison of EKG data for informing a user of the hearts conductive activity [Fig. 23], as in claims 29 and 30.

Claims 1, 12, 19, and 36 are rejected under 35 U.S.C. 102 (b) as being anticipated by Kohl et al. (Phil. Trans. R. Soc. Lond. A, 2000, Vol. 358, p. 579-610).

Kohl et al. present methods for the computational modeling of biological systems using “in silico” organs. In particular, In particular, Kohl et al. teach the following aspects of the instantly claimed invention as they read upon Species A, B, and C: analytical models of the heart are provided that are based on biological measurements that include normal and abnormal ECG [p.597, Section (e)], as in claims 1, 19, and 36 and Specie C. Simulating model operation under normal and abnormal heart conditions (i.e. operational modes) [Fig. 3 and 9], which is a

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teaching for selecting operational modes such that the output produced matches measurement data, as in claim 1, since each model is based on specific biological measured data [p.581, ¶2]. Furthermore, arrhythmic behavior is determined by operating models using cellular metabolism information [p.586, ¶2] and [Fig. 2], which is broadly interpreted as deducing a condition of arrhythmia, as in claims 1 and 12 and Specie A. Kohl et al. also disclose a similar method used by the Auckland group to produce a biophysically based coupled heart-lung model for use in drug discovery and the clinical diagnosis and treatment of cardiopulmonary disease [p.610], which equates to simulation of the cardiopulmonary system, as in claim 36 and Specie B.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1, 2, 5-12, 15-19, 22-25, 29-33, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine (US 2004/00064298; Filed Sep. 26, 2003), in view of Robb et al. (Computerized Medical Imaging and Graphics, 2000, Vol. 24, p.133–151).

Levin teaches a virtual patient model for simulating the onset, diagnosis, and treatment of all major medical conditions via a medical instructional console. In particular, Levine teaches the following aspects of the instantly claimed invention as they read upon Species A, B, and C:

Operating exemplary simulated organs including a beating heart and lungs, as in claims 1, 2, 7, 11, 17, 19, 33, and 36, and Specie C. Selecting an operational mode for generating a virtual patient based on obtaining patient data or operational parameters of the selected operational mode [0078]; an operation mode for simulating normal and abnormal heart rhythms (i.e. arrhythmias) [0084] with a selectable cardiac monitor, wherein rhythms are replications of patient data to simulate an actual human heart [0084], which is a teaching for obtaining data and selecting an operational mode as in claims 1, 2, 12, 32, and Specie A. A communications network for connecting multiple users at multiple computer terminals to the simulation computer comprising simulated organs (i.e. server) [Fig. 3] and [0023] using a wireless communications system [0065], as in claims 5, 6, and 31. Virtual patients with abnormal and normal symptoms for the diagnosis of a medical condition [0072], as in claims 9-11 and 15-17. Simulation of the thorax and monitoring the heart rhythm of a patient [Fig. 7] using three sensors and performing testing including EKGs [0086], as in claims 8, 22, 23, and 25. Displaying information to a user for detecting medical conditions using a diagrammatic schematic showing electrical conduction waveforms within the heart using EKG [0070] and

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[Fig. 9 and 10], as in claim 29, 30, 31. Simulation of the cardiopulmonary system in a virtual patient [Fig. 14] and [0085], as in claim 36 and Specie B.

Levine does not specifically teach the “preprocessing” biological data, as in claim 18, or “six ECG sensors” as in claim 24. However, it would have been obvious to one of ordinary skill in the art to increase the number of EKG sensors to improve simulation accuracy by acquiring more data, as in claim 24.

Robb et al. teach a method for simulated visualization of patient specific organs using data that is obtained from MRI examinations [p.133, Col. 1 and 2], wherein organs specifically include the heart and thorax [Fig. 3]. In particular, Robb et al. teach that “pre-processing” of data after it has been obtained is essential is required in order to prepare data for modeling [Section 3: Methods], as in claim 18.

Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to practice the method of Levine using an additional preprocessing step, as taught by Robb et al., to preparing reliable and reproducible models of simulated organs, resulting in the practice of the instant claimed invention with predictable results. One of ordinary skill in the art would have been motivated to perform preliminary processing on any data for use in the simulation model in order to properly prepare it for modeling or to reduce the dataset to the desired specific anatomic structure, as taught by Robb et al. [Section 3: Methods].

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### CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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